December 7, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear Dr. von Eschenbach:

I am writing to follow up on my previous letters to you regarding the recent surge in the use of phenylephrine oral nasal decongestants, which have been marketed as alternatives to the pseudoephedrine products now exclusively sold behind the counter pursuant to anti-methamphetamine provisions included in the 2006 reauthorization of the Patriot Act.[1] In my September 22 and October 23 letters, I highlighted the fact that Schering Plough had recently conducted and completed a study comparing phenylephrine to both placebo and to pseudoephedrine.[2] Since the writing of those letters, the company has made the results of the study public,[3] and, I understand, provided these results to you as well.

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[1] USA PATRIOT Improvement and Reauthorization Act of 2005, Pub. L. No. 109-177, enacted March 9, 2006. The Combat Methamphetamine Epidemic Act of 2005 (H.R. 3889) was passed as Title VII of the Patriot Act.

[2] U.S. National Institutes of Health, ClinicalTrials.gov, "The Effects of Phenylephrine Compared With Those of Placebo and Pseudoephedrine on Nasal Congestion in Subjects With Seasonal Allergic Rhinitis (SAR) (Study P04579)" (online at: www.clinicaltrials.gov/ct/show/NCT00276016;jsessionid=1B43B1BF395CA89630495B0A166321ED?order=1) (accessed on October 17, 2006).

[3] PhRMA Clinicalstudyresults.org, *Protocol P04579: Crossover Study of the Decongestant Effect of Phenylephrine Compared With Placebo and Pseudoephedrine as Active Control in SAR Subjects Exposed to Pollen in the Vienna Challenge Chamber* (online at: www.clinicalstudyresults.org/drugdetails/?company_id=11&inn_name_id=394&sort=c.company_name&page=1&drug_id=1683)

As you now know, the Schering study found that phenylephrine at the FDA-monograph dose was not significantly different than placebo and was significantly less effective than pseudoephedrine in decreasing nasal congestion. Now is the time for FDA to reexamine whether phenylephrine works.

In response to my previous letters, you have indicated that you would not convene a meeting of the Nonprescription Drugs Advisory Committee to examine the effectiveness of phenylephrine because you were unaware of any data contradicting that considered by the advisory panel originally convened in 1976 to evaluate phenylephrine. The Schering study provides strong evidence that the conclusions of the original panel need to be re-examined. FDA, along with the input of the Nonprescription Drugs Advisory Committee, should promptly make a serious scientific inquiry into whether there is an effective, and safe, dose of phenylephrine.

FDA must ensure Americans that it has done everything in its power to prevent them from needlessly wasting their hard-earned dollars on medicines that do not work.

Please respond to this letter no later than December 22, 2006.

Sincerely,

Henry A. Waxman
Ranking Minority Member